REMARKS

Rejection of the Claims Under 35 U.S.C. §112, first paragraph

Claims 127-129 recite polypeptides comprising specifically identified amino acids. Support for the peptides of SEQ ID NO:2 is explicit on pages 60-61 of the specification.

Claim 124 recites an isolated polypeptide which is encoded by a polynucleotide that hybridizes under stringent conditions to the complement of a DNA sequence encoding a *Neisseria* surface polypeptide that is resistant to proteinase K and has an apparent molecular weight of 22 kd. Claim 124 and the claims dependent thereon encompass polypeptides that are highly structurally related to the *Neisseria* polyeptide because the encoding polynucleotide hybridizes under stringent conditions to the complement of a DNA sequence encoding the *Neisseria* polypeptide. Typical stringency hybridization conditions are exemplified in the specification in, e.g., Example 4 (see p.46, lines 11-25). One of ordinary skill in the art would readily recognize that such hybridization conditions are conventional in the art.

Claim 124, and all other claims, also require that the polypeptide be "antigenic." Such a property is more than sufficient to define the "function" of the claimed polypeptides as sought by the examiner. Any pharmacological or biological property is sufficient for such purposes under long-standing case law. The patent system is designed to foster early disclosures. See, e.g., *Fujikawa v. Wattansin*, 79 F3d 640, 39 USPQ2d 1895 (Fed. Cir. 1996).

Furthermore, the current claims are in conformance with the written description guidelines cited by the examiner. Claims having the kind of breadth recited here (hybridizing under stringent conditions, for example) are appropriate according to recent presentations of the PTO, as long as a full sequence is disclosed along with a biological function such as antigenicity. Since both a full sequence and an appropriate biological function are disclosed and claimed, withdrawal of the written description rejection is in order.

The same conclusion applies to the fragment claims, each of which contains an epitope as determined by applicants and described on pages 60-61 of the specification.

The antigenicity of the corresponding epitope clearly provides the necessary function such that the full length of the fragment peptide is claimable under the PTO's own guidelines.

As for enablement, it is well established that absolute predictability of success is not required for the specification to enable the skilled artisan to make and use the claimed subject matter. Some experimentation may be required to make the claimed invention, and that experimentation may entail a significant amount of work, provided that the work is routine and reasonably predictable, *In re Wands*, 858 F.2d 731, 8 USPQ 1400 (Fed. Cir. 1988). The specification discloses routine assays for determining whether the polypeptides of the invention are suitable for use as a vaccine, i.e. whether the protein confers protection against subsequent bacterial challenge (specification at page 17, lines 13-23 and Example 6 at page 51). Nothing more is needed.

The mere possibility that some surface proteins or epitopes of a given bacterium might not be sufficiently antigenic to provide immunity, as alleged by the examiner, is not enough to establish lack of enablement. Applicant's specification is presumptively accurate. Applicants state that the claimed polypeptides and fragments are antigenic and can be used as components of vaccines. To overcome the presumptive accuracy, the examiner needs reasons or evidence beyond the mere allegation that some <u>other</u> proteins might not have such a characteristic. What is needed to establish lack of enablement would be reasons to doubt the accuracy of applicant's statement as it pertains to the subject matter currently claimed, not other proteins from the same bacterium which might have other properties. The experiment noted by the examiner at the bottom of page 6 of the office action provides strong evidence of the existence of enablement, not the lack thereof simply because other tests were not performed.

The specification provides considerable guidance to make and use all the polypeptides encompassed by the claims. Accordingly, the present claims fully comply with 35 U.S.C. §112, first paragraph.

<u>Rejection of the Claims Under 35 U.S.C. §112, second paragraph</u>

Claim 124 stands rejected for allegedly being indefinite under §112, second paragraph. Applicants respectfully traverse.

As noted above, exemplary hybridization conditions are detailed in the specification in Example 4 (see p.46, lines 11-25). One of ordinary skill in the art would readily recognize that these hybridization conditions (50% formamide solutions with a temperature of 42^0 C) are routine in the art.

Rejection of the Claims Under 35 U.S.C. §102

Claims 124, 133-137, 170 and 172 stand rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Merks et al. (WO 94/05703). Applicants respectfully traverse.

Merks discloses a monoclonal antibody to a 20kd cell surface protein of *Neisseria meningiditis*. There is no disclosure or teaching that the 20 kd surface protein disclosed in Merks is resistant to proteinase K treatment or is related in any way to the 22 kd *Neisseria* polypeptide which is resistant to proteinase K treatment of the instant invention. The Examiner does not distinguish between the 20 kd Neisseria surface antigen of Merks and the 22kd *N. meningiditis* surface antigen of the present invention. Merks clearly provides insufficient disclosure to compel the conclusion that the 20kd protein disclosed therein is the same antigen as the presently claimed polypeptide. It is well established that the Examiner must shoulder the burden of providing evidence that a property allegedly inherent in the prior art necessarily flows from the art teachings. The mere fact that a certain thing may result from a given set of circumstances is not sufficient, *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA 1981). There is clearly no basis to state that the proteins are the same. Attached hereto are remarks filed in the parent case which led to withdrawal of a similar anticipation rejection based on Merks et al. The mentioned references are available in the parent.

Claims 124 and 133-135 stand rejected for allegedly being anticipated by Bhattacharjee et al. Applicants respectfully traverse.

Bhattacharjee et al discloses a surface antigen (H.8) purified from *N. meningiditis* Group B. Bhattacharjee discloses that the purified H.8 surface antigen preparation exhibited three bands on an SDS-PAGE gel with a major band at 27 kd (page 776, second column and Figure 1). Additionally, the amino acid composition of the purified H.8 antigen reveals that alanine (41.4%) and proline(26.6%) are major consituents of the

protein and no aromatic or sulfur-containing amino acids are present (page 775, column 1).

By contrast, the *Neisseria* protein of the instant invention has a molecular weight of 22 kd. As for SEQ ID.2, it also has a significantly different amino acid composition. Careful scrutiny of the amino acid sequence for the polypeptide of SEQ ID NO:2 (shown in Figure 1) reveals that 16 of the 155 total amino acid residues are alanine (about 10%) and that 5 of the 155 total amino acid residues are proline (less than 4%). Moreover, the polypeptide of SEQ ID NO:2 has aromatic residues, e.g. phenylalanine. Clearly, the polypeptide of the instant invention is NOT the *Neisseria* surface antigen disclosed in Bhattacharjee. The Examiner
has provided no evidence which would indicate otherwise.

The rejection of the claims under 35 U.S.C. §102 is improper and should be withdrawn.

In view of the above remarks and amendments, favorable consideration of the application is courteously requested. An early notice to this effect is earnestly solicited. However, if there is any remaining issue(s) which can be expeditiously resolved by a telephone conference, the Examiner is courteously requested to telephone the undersigned at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to the Deposit Account NO. 13-3402.

Respectfully submitted,

Anthony J. Zelano, Reg. No. 27,969
Millen, White, Zelano & Branigan, P.C.

Arlington Courthouse Plaza I
2200 Clarendon Blvd., Suite 1400
Arlington, Virginia 22201
direct dial: (703) 812-5322
email: mccarthy@mwzb.com

Date filed: June 30, 2003

K:/Pharma/147C1/reply to OA 12-31-02.word